April 19, 2000

1070 '00 APR 26 P2:25

Dear Food and Drug Administration,

I had been sent the "Guidance For Industry, Labeling Guidance for Estrogen Drug Products....Prescribing Information for Healthcare Providers and Pattien Labeling". Draft Guidance.

It says that, "This guidance document is being distributed for comment purposes only. This guidance document represents the Agency's current thinking on estrogen class labeling" As a very concerned consumer, I have some important concerns and comments. I ask the following questions as to the confusion caused in the enclosed proposed estrogen drug labeling guide. I hope you will please reply, and consider changing the labeling for the sake of consumer clarity. This labeling as you sent is very confusing, and more often misleading.

UNDER,
INDICATIONS and Usage- #4. What does this mean that estrogens are used for the treatment of breast cancer (for palliation) in appropriately selected women and men with metastatic disease? Are you talking about the estrogens Premarin, Prempro or Premphase for this treatment? Or are you talking about the estrogen Tamoxifen? Can you be more specific please? For women with cancer, what classifies a woman as "appropriately selected?

6. Under the same heading of, INDICATIONS and Usage.....Prevention and management of postmenopausal osteoporosis. Can estrogen alone prevent osteoporosis? If a woman sitting in a chair, or bedridden, and she takes ERT, without eating, without vitamin or calcium supplements.....Can estrogen alone prevent osteoporosis? What clinical studies have proven that ERT or HRT prevents or even manages osteoporosis for all women, or even some of the women who are prescribed it? Being long-term use, what is the "safety" evidence of clinical studies conclude with the increasing risk of cancers?

Under CONTRADICTIONS,
#2. "Known or suspected cancer of the breast, (except for appropriately selected patients being treated for metastatic disease). Are you talking about the very same estrogen for both sides of your statement? ERT promotes metastasis, so do you mean, don't take it if you think you have cancer, but then it is confusing because you say "yes do take estrogen for metastatic disease. Please clarify if you are talking about the same ERT estrogen in the statement or ERT in the beginning, and change to Tamoxifen in the second part, to treat metastatic cancer. What does this mean.... please clarify. For what purpose would ERT which causes cancer metastasis, be prescribed to treat metastasis?

#3. Known or suspected estrogen-dependent neoplasia. Why not call neoplasia, "cancer" for the layperson. What is the purpose of the above statement? Why are the areas of estrogen-caused cancer metastasis not listed, i.e., liver, lungs, bone and brain, and wherever else estrogens cause metastasis. How sure can a person be that she does not

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We believe that including this information in the Federal Register notice will provide for a more open process and facilitate discussion on the guidance document.

We request that similar revisions be made in §10.115(g)(3)(i)(A) to read as follows:

> "§10.115(g)(3)(i)(A) Publish a notice in the **Federal Register** announcing that the draft guidance document is available together with the reason(s) the guidance document is necessary and why the document has been implemented without prior public comment."

This information should be made available to the public and will facilitate discussion on the guidance document.

We believe that the development and issuance of a Level 2 guidance document should be announced in the Federal Register and suggest that a new (A) be added to §10.115(g)(4)(i) with the existing proposed paragraphs being redesignated as (B), (C), and (D).

> "§10.115(g)(4)(i)(A) Publish a notice in the **Federal Register** announcing that the draft guidance document is available together with the reason(s) the guidance document is necessary;"

The proposed §10.115 (n)(2) states:

> "Once a year, FDA will publish its comprehensive list of guidance documents in the **Federal Register**. The comprehensive list will identify documents that have been added to the list or withdrawn from the list since the previous comprehensive list."

As this is meant to be a comprehensive list, we suggest the language be amended to include identification of documents that have been revised or are currently up for consideration for revision. The amended language would read as follows:

> "Once a year, FDA will publish its comprehensive list of guidance documents in the **Federal Register**. The comprehensive list will identify documents what have been revised, withdrawn, added to the list, or are under consideration for revision since the previous comprehensive list."

Thank you for providing this opportunity to comment on this proposal.

Sincerely,

Allen W. Matthys, Ph.D.
Vice President
Regulatory Affairs

NFPA
The Food Safety People

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